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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,332	02/13/2006	Gunter Stempfer	BPG-33315A/BCK	6279
72554	7590	06/15/2010		
SANDOZ INC 506 CARNEGIE CENTER PRINCETON, NJ 08540			EXAMINER WEGERT, SANDRA L	
			ART UNIT	PAPER NUMBER
			1646	
			MAIL DATE	DELIVERY MODE
			06/15/2010 PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/568,332

Applicant(s)

STEMPFER ET AL.

Examiner

SANDRA WEGERT

Art Unit

1646

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4-9, 12, 13, 15 and 17-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13, 15 and 17-24 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-9 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Application, Amendments, and/or Claims

The amendments and Remarks, sent 3 May 2010, have been entered into the record. Claims 13 and 15 have been amended. Claims 3, 10, 11, 14 and 16 are cancelled. Claim 25 is new.

Claims 1, 2, 4-9, 12, 13, 15 and 17-25 under examination in the Instant Application.

Withdrawn Objections and Rejections

Claim Objections -

The objection to claims 14 and 16-24 for depending from a rejected base claim is *withdrawn*. Applicants cancelled claims 14 and 16 and amended independent claims such that claims 17-24 no longer depend from rejected claims (3 May 2010).

Claim Rejections - 35 USC § 112- second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 13 and 23 under 35 U.S.C. § 112, second paragraph, is *withdrawn* based on applicants' amendments (3 May 2010).

35 USC § 112, first paragraph - Written Description.

The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claim 15 under 35 U.S.C. §112, first paragraph, for lack of written description for "agent," is withdrawn, based on applicants' amendment (3 May 2010).

Maintained/New Claim Rejections/Objections

Claim Rejections- 35 USC § 102

The following is a quotation of the appropriate paragraph of 35 U.S.C. 102 that forms the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims **1, 2, 4-9 and 12** *remain* rejected under 35 U.S.C. 102(b) for being anticipated by Bochner et al (1987, US Patent 4,680,262). This rejection also applies to new claim **25**. The Bochner patent discloses a method for the preparation of growth hormone or any peptide of interest from transformed *E. coli* cells. The polypeptides are described as being injected into the *periplasm* of the transformed *E. coli* host cells (see Title and Abstract) as recited by the instant independent claims. In at least two examples, the patent discusses extraction of the polypeptide of interest by *osmotic shock* (column 10, see Example 4; column 11, Example 7), as recited in

claims 1, 2 and 25 and encompassed by all claims. In addition, Bochner et al discuss agents used for osmotic shock, such as *sucrose* (column 5, line 32), as well as typical concentrations used for fermentation extraction of proteins, such as 20% sucrose (column 5, line 33).

Applicants have argued against Bochner being used as prior art because they contend that Bochner did not apply an osmotic shock to the cells in the fermentation medium, and in fact argue that Bochner *denigrates* the use of osmotic shock as a means of disrupting bacterial cell membranes (Remarks, 3 May 2010, pp. 8-10). Applicants also argue that Bochner did not apply an osmotic shock directly to the cells in the "fermentation medium itself" (Remarks, p. 9, second paragraph).

Applicant's arguments have been fully considered but they are not persuasive for the following reasons:

It is true that Bochner does discuss the differences between freezing recombinant cells to extract proteins and using osmotic shock for the same purpose (see the discussion at column 5, third full paragraph). In fact, many of the examples given in the patent were performed in order to demonstrate which of the two was the superior method. In general, Bochner claims that thawing/freezing cells produces a better yield of the polypeptide of interest, especially for larger batches (column 12, last paragraph before the claims). Bochner does not "denigrate" the use of osmotic shock, however, as evinced by the use of that very technique in examples 4 and 7, and by statements such as: **"it should be understood that any method for causing the outer membrane of the cell to become permeable to the periplasmic protein can be used with**

killed cells," during the discussion in the patent about the use of osmotic shock (column 5, line 33).

As to the point that Bochner did not add the osmotic agent directly to the fermentation medium, Example 4 in the patent explains that osmotic shock was used to disrupt the cells; therefore, it can be presumed that an agent was added *to the medium comprising the cells* or the cells would not have been osmotically shocked by the agent.

Conclusion:

Claims 1, 2, 4-9, 12 and 25 are rejected for the reasons cited above. Claims 13, 15 and 17-24 are allowable.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (571) 272-0895. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Nickol, can be reached at (571) 272-0835.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

/SLW/
5 June 2010

/Dong Jiang/
Primary Examiner, Art Unit 1646